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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/721,318	11/25/2003	Robert L. Dow	17082AZ (PC10118C)	7093

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EXAMINER

DAVIS, ZINNA NORTINGTON

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 05/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/721,318	Applicant(s) DOW ET AL.	
	Examiner Zinna Northington Davis	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 February 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-104 is/are pending in the application.
- 4a) Of the above claim(s) 50-54, 57, 58 and 100-104 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-49, 55, 56, and 59-99 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>4/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. In the response filed February 25, 2005, Applicants have elected the compound of Example 76 as the preferred species.
2. Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

Response to Applicants' Remarks

About the Election Requirement

Applicants respectfully request that this Restriction Requirement be withdrawn since it is not in compliance. Applicants further state that the United States Patent and Trademark Office has not even shown in the alleged Restriction Requirement that the application contains several patentably distinct species. More specifically, the United States Patent and Trademark Office did not show that the various species alleged to be patentably distinct are independent. Moreover, the United States Patent and Trademark Office did not show that the various claimed species are patentably distinct. It just made mere conclusions that the species in the instant specification are patentably distinct without any rationale or reasoning. The United States Patent and Trademark Office has thus not met its burden.

It is the Examiner's position:

- The various chemical compounds with the definition of Formula I are independent and patentably distinct. See the radicals defined by A. At claims 87-100, see the various method of using the compounds of Formula I.
- See DiMaio et al. (Reference U) which teach a similar class of tricyclic compounds. These chemical compounds are intermediates in preparing pharmacological compounds. See page 2699, 1st column.
- Though these similar compounds are related in chemical structure, the methods of using are dissimilar.
- As such, the Office has met the burden to show that the compounds are independent and patentable distinct.

Applicants further state that restriction requirements issue only with the proper statutory authorization, because patents issuing on divisional applications, which are filed to prosecute claims that the Examiner held to be independent and distinct can be vulnerable to legal challenges, allege double patenting. The third sentence of 35 U.S.C. §121, which states that a patent issuing on a parent application "shall not be used as a reference" against a divisional application or a patent issued thereon, does not provide comfort to Applicants against such allegations. The Court of Appeals for the Federal Circuit has declined to hold that 35 U.S.C. §121 protects a patentee from an allegation of same-invention double patenting. Further, the imposition of a Restriction Requirement with inadequate

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authority can lead to situations in which an Applicant's legitimate patent rights are exposed to uncertainty and even extinguished. Accordingly, to protect a patentee's rights and to serve the public's interest in the legitimacy of issued patents, Applicants respectfully request the Examiner not to require restriction in cases such as the present application where various aspects of a unitary invention are claimed.

It is the Examiner's position:

- When examining an application for which applicants pay a filing fee, the scope of the claims should be drawn to a single invention (a compound, pharmaceutical composition, a method of use, and process of making).
- The Examiner must search and examine *a single inventive concept*.
- If more than a single inventive concept is filed in an application, a restriction requirement is imposed.
- The nonstatutory double patenting rejection is made to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees.
- This rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute).
- The Restriction Requirement is not made to exclude patent rights.

Applicants respectfully request that in view of increased official fees and the potential limitations of Applicants' financial resources, a practice which arbitrarily imposes a Restriction Requirement may become prohibitive, and thereby

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contravenes the constitutional intent to promote and encourage the progress of science and the useful arts.

It is the Examiner's position:

- The restriction requirement is not made to increase official fees or limit Applicants' financial resources.
- The restriction requirement is made so that the Examiner can search and examine *a single inventive concept*.
- Because multiple inventions are claimed, a restriction requirement is imposed.
- As such, the restriction requirement is deemed proper, and hereby made FINAL.

3. Claims 1-49, 55, 56, and 59-99 are Markush claims which are generic to the elected invention. These Markush claims lack unity of invention. Accordingly, the Markush type claim will be examined fully with respect to the elected species and further to the extent necessary to determine patentability. See MPEP 803.02.

4. Claims 1-49, 55, 56, and 59-99 are objected on the grounds that the claims are drawn to an improper Markush group. In re Harnish, 206 USPQ 300, states that a unity of invention exists where compounds included within a Markush group(1) share a common utility and (2) share a substantial structural feature disclosed as being essential to that utility. In the instant case, the claimed subject matter does not share a substantial structural feature disclosed as being essential to that utility.

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The requirement for a proper Markush claim is that it includes only substances that in their physical, chemical and physiological characteristics are functionally equivalent. The members of the instant Markush groups possess widely different, physical and chemical properties. The compounds are not considered functionally equivalent and are so diverse that they demonstrate dissimilar and unrelated properties. The mere fact that there is structural similarity in pharmaceutical agents is not in itself reason to render all the embodiments functionally equivalent.

The improper Markush groups are A, B, C, D, E, F, X, and R₁.

5. The examined subject matter is as follows:

A compound of formula I wherein A is A-1; D, E, and F are C; X is CH₂; R₁ is Z-aryl; and Z is absent. The radicals not defined above are as recited in claim 1. Amending the claims to the examined subject matter would overcome the improper Markush rejection.

6. The non-statutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 1-49, 55, 56, and 59-99 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-60 of U.S. Patent No. 6,380,223. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claimed subject matter overlaps. Compare the claimed subject matter versus the instant claims.

8. Claims 1-49, 55, 56, and 59-99 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-82 of U.S. Patent No. 6,699,893. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claimed subject matter overlaps. Compare the claimed subject matter versus the instant claims.

9. If the examined subject matter is extended beyond the elected species, the following rejection would be applicable.

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1-4 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by DiMaio et al (Reference U).

The instantly claimed compound is disclosed. At page 2699, see compound 9. The claims are fully met when A is A-1; D, E, and F are C; X is CH₂; and R1 is Z-het.

12. The Information Disclosure Statements filed April 28, 2005 have been considered. The references alone or in combination form do not teach nor suggest structurally similar compounds as the examined subject matter.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zinna N. Davis whose telephone number is 571-272-0682.

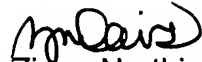
14. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications.

15. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

16. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Zinna Northington Davis
Primary Examiner
Art Unit 1625

Znd
05.13.2005